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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/144,886	08/31/1998	JAMES D. MARKS	2307E-826US	5313

22798 7590 04/10/2003

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EXAMINER

MINNIFIELD, NITA M

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 04/10/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/144,886

Applicant(s)

MARKS ET AL.

Examiner

N. M. Minnifield

Art Unit

1645

-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 and 78 is/are pending in the application.
- 4a) Of the above claim(s) 2,4,5,13-16 and 31-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,6-12,17-30,36-43 and 78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 2 sheets
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election with traverse of species—clone C25, C25VH regions given by SEQ ID NO:63 and C25 VL region given by SEQ ID NO:87 in Paper No. 26 is acknowledged. The traversal is on the ground(s) that the Examiner has not set forth reasons for the species election in view of the fact the all claims (1-43) have been previously examined. This is not found persuasive. It is noted that Applicants amended (paper filed December 13, 2001) claims 6-10, 17-29 and 36-42 to specifically recite multiple possibilities of the claimed antibody. Examiner agrees that claims 1 and 24 are generic. Claims 1, 3, 6-12, 17-30, 36-43 and 78 will be examined as they read on the elected species as set forth above.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 2, 4, 5, 13-16 and 31-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 26.

3. All rejections have been withdrawn in view of Applicants' amendment and/or comments, with the exception of those discussed below.

4. Claims 6-12, 17-30, 36-43 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are

vague and indefinite in the recitation of "nucleotides". The sequences set forth in Table 4 and specifically SEQ ID NO:63 and 87 set forth amino acid sequences not nucleotide sequences. Does Applicant mean amino acids 31-35 of SEQ ID NO:63 for example?

5. The rejection of claims 1, 3, 6-12, 17-30, 36-43 and now claim 78 under 35 U.S.C. § 102(a) as anticipated by Amersdorfer et al, 1997 is maintained. This rejection is maintained for essentially the same reasons as the rejection of claim under this statutory provision, as set forth in the last Office action.

Applicants' arguments filed December 13, 2001, have been fully considered but they are not deemed to be persuasive. Applicants have asserted that this reference is Applicants own work within the year before the application filing date and that it cannot be used as prior art. Applicants state that upon a showing of otherwise allowable subject matter, Applicants will provide Katz declarations. It is noted that this rejection will be maintained until such declarations have been received.

6. Claims 1, 3, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al (Infection and Immunity, May 1997, 65/5:1626-1630).

Chen et al disclose an isolated single chain antibody and that these antibodies bind to BoNT/A and neutralizing antibodies against botulism poisoning (abstract; p. 1627; p. 1626; p. 1630).

7. Claims 1, 3, 6-12, 17-30, 36-43 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is apparent that monoclonal antibody clones set forth in the claims are required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of each clone. See 37 C.F.R. 1.802.

The specification does not provide a repeatable method for obtaining the monoclonal antibody clone C25 as claimed and it does not appear to be readily available material. Deposit of the clone would satisfy the enablement requirements of 35 U.S.C. § 112. If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. 1.808.

If the deposits have not been made under the provisions of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an

attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposits will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

© the deposits will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

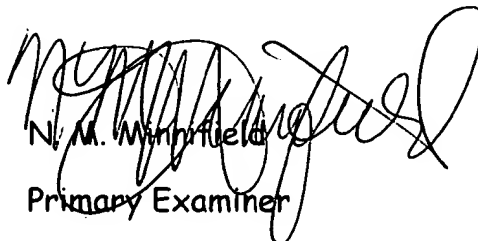
(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

8. No claims are allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM

March 27, 2003